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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,978

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Jens-Peter Seher

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
595 MINER ROAD
CLEVELAND, OH 44143

EXAMINER

SU, SUSAN SHAN

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

09/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,978	Applicant(s) SEHER ET AL.	
	Examiner SUSAN SU	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10 February 2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

Claims 1-11 are pending and examined on the merits.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The disclosure is objected to because of the following informalities: typographical error on page 5 line 15 where “membrane 12” should be changed to --membrane 18--.

Appropriate correction is required.

Drawings

3. The drawings are objected to because the numbering for the features 90 and 94 are switched. In the Specification page 6 line 32 to page 7 line 3, the Applicants refer to the coating as number 90 and outer side as 94. Fig. 4 shows 90 as the outer side and 94 as the coating. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

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drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 provides for the use of the closure device of Claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-4 & 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wesseler (US 5,534,228) in view of Tingey et al. (US 2002/0168530, "Tingey").

With regard to Claims 1, 6, & 11, Wesseler teaches a closure device (as shown in Fig. 4, which is capable for connection to a vessel and act as a closure device) for a container, comprising a filling device (3, 3A, 3B, & 4 combined) that can be attached to an opening of the container and a closure means (4 and 3) that is attached to the filling device in such a way that the opening of the container is sealed if the filling device is attached to the opening. However, Wesseler does not teach that the closure means is at least partially coated with polytetrafluoroethylene on one side that is accessible from outside the container in the assembled state of the filling device on the container.

Tingey teaches providing a coating of polytetrafluoroethylene (1) on the outside surface

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of a closure means (20) of a closure device (10). Tingey also teaches using the closure device in an analytical device ([0003] where the closure is used for catheters, which is an analytical device). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wesseler with Tingey for the purpose of allowing a smoother fit when the closure means is pushed in.

With regard to Claim 2, Wesseler also teaches that the closure device (4) can be pierced by a sharp object (since it can be pierced by a blunt object as shown in Fig. 6, it can be pierced by a sharp object), in particular by a needle tip.

With regard to Claim 3, Wesseler also teaches that the closure means is a membrane (4).

With regard to Claim 4, Wesseler also teaches that the closure means is a septum (4).

With regard to Claim 7, Wesseler also teaches that the closure means is composed of silicone (Col. 4 line 28).

With regard to Claim 8, Wesseler also teaches that the closure means comprises a first region (4) that comprises soft material having good adhesive properties (silicone elastomers have adhesive properties) and a second region (3) that encloses the first region. Wesseler does not teach that the second region comprises a hard material. Tingey teaches that the second region (housing or hub 10) of a closure means (10 & 20 combined) comprises hard material ([0003], "rigid"). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wesseler with Tingey for the purpose of having a closure device with structural integrity.

With regard to Claim 9, Wesseler also teaches that the filling device has a Luer closure device (30) that can be attached to the opening of the container.

With regard to Claim 10, Wesseler also teaches a collecting space (between 4 & 3 in Fig. 4) for receiving a fluid that can be introduced into the collecting space through the closure means.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wesseler and Tingey as applied to claim 1 above, and further in view of Healy (US 5,425,465). Wesseler and Tingey do not expressly teach that the closure means is a duck-bill valve device. Healy teaches a duck-bill valve (Fig. 3A) as a closure means for a medication container. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Wesseler and Tingey with Healy for the purpose of preventing backflow of liquid from the container.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Smith (US 2002/0130100) teaches a closure device with a membrane and a septum as closure means and a collecting space.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761